

REMARKS

Claims 1 through 49 remain pending in the application. Applicants appreciate the Office's indication that claims 34-44 are allowable and that claims 6-11 and 22-27 would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Rejections under 35 U.S.C. § 102(b)

Claims 1-5, 12-14, 18-21, 28-30 and 45-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by Mayer (U.S. Patent No. 5,820,601). Applicants traverse this rejection on the following grounds.

Claims 1 and 18 recite a movable element comprising a head defining a bore forming a part of the fluid passageway through the connector, the head being configured such that when the movable element is in the second position, the bore self-opens to permit fluid flow. Similarly, independent claim 45 recites a method for controlling the flow of fluid comprising moving a movable element that is positioned within the housing from a first position to a second position, the movable element comprising a head with a bore that is closed to prevent fluid flow through the housing when the movable element is in the first position and is self-opening when the movable element is in the second position to permit fluid flow. This self-opening feature of the bore is demonstrated in the embodiment shown in FIG. 5 where the bore 64 of the top portion 60 of the head 54 is open. FIG. 8 shows the bore 64 closed when the movable element 38 (FIG. 7) is positioned within the housing 22 in the first position. In this position, the head 54 is within the narrowed Luer taper portion 100 (FIG. 7) of the housing and the narrowed portion 100 has caused a compressive force to be exerted against the top portion 60 of the head 54, thereby causing the bore 64 to be closed (see Spec., p. 14, l. 29 – p. 15, l. 2). As a male cannula 130 is inserted into the connector 20 as shown in FIG. 10, the movable element 38 is moved to the second position wherein the head 54 is within the wider

center portion 102 of the housing, the compressive force from the narrowed portion 100 has been removed and the bore 64 once again self-opens as in FIG. 5.

Mayer fails to disclose or suggest a movable element having a head with a bore that self-opens when the movable element is in the second position to permit fluid flow. Instead, Mayer discloses a reseal member 58 comprising a resilient body 60, with an aperture 80 at its proximal end 64, and a radial leaf spring 84 disposed inside the body 60 (see FIG. 3). As the reseal member 58 is moved from a first position to a second position to permit fluid flow, the radial leaf spring 84 is distally advanced over a dilator projection portion 40 causing the leaf portions 88 of the spring 84 to flex outwardly and facilitate radial expansion of the aperture 80 to its open configuration (see FIG. 4, col. 4, lines 9-15 and col. 9, lines 9-14). Thus, rather than self-opening, the aperture is forced open by other devices. Specifically, due to the dilator projection portion 40, the leaf spring 84 moves outwardly against the resilient body 60 to cause the aperture 80 to open, as shown in FIG. 4. In FIG. 5 of Mayer, the aperture 80 appears to be in the closed configuration in its normal or resting state. In applicant's claimed invention, the bore of the head self-opens in the second position permitting the movable member to be formed of a single piece construction without the need for a leaf spring, unlike Mayer, to open the aperture. Such a design avoids the relatively more complex valve mechanism in which a leaf spring is incorporated within a flexible member which, as discussed in the specification at page 4, lines 23 to 28, adds some manufacturing concerns as well as at least one additional part, i.e., the leaf spring. Because Mayer fails to disclose or suggest a movable member comprising a head defining a bore that self-opens to permit fluid flow, as is claimed in independent claims 1, 18 and 45, applicants respectfully submit that all pending claims are patentable over Mayer.

In addition, dependent claims 12 and 28 recite that the housing includes a narrowed region adjacent the first port, the narrowed region being dimensioned so as to cause the bore of the head to close. In Mayer, removal of distally directed pressure from the reseal member 58 causes the radial leaf spring 84 to be withdrawn from over the dilator projection portion 40, facilitating the resilient return of the reseal member 58 to its

first position which causes the aperture 80 to resiliently return to its closed configuration (see col. 9, lines 58-65). There is no mention in Mayer that the housing of its needleless injection site is dimensioned so as to cause the bore of the head to close when it is in the first position. Thus, Mayer does not disclose a housing that includes a narrowed region dimensioned so as to cause the bore of the head to close, as is recited in claims 12 and 28, and applicants respectfully submit that these claims are further patentable for this reason.

Claim 18 also recites that the movable element comprises a compressible section defining an inner conduit forming a part of the fluid passageway through the connector and that the inner conduit of the compressible section is configured such that fluid may continuously flow through the entire inner conduit when the movable element is in the second position. Dependent claim 4 recites similar subject matter and claim 45 recites the step of causing fluid to flow continuously through the entire inner conduit when the movable element is located at the second position. Mayer does not disclose or suggest these features. In Mayer, the resilient body 60 of the reseal member 58 forms a reservoir 100 when the needleless injection site 10 is in the second or open position (see FIG. 4). As is evident in FIG. 4, the reservoir 100 is not in the direct flow path of fluid which travels from the open aperture 80 and through fluid passage 56. As discussed in applicant's specification at page 4, line 28 through page 5, line 2, such a reservoir-type system does not permit continuous flow through the entire expandable flexible body section because fluid flows into the reservoir and is retained there until the valve is returned to its unaccessed state. For instance, Mayer states:

In particular, the open aperture 80 is co-axially aligned with the fluid passage 56, thus creating a continuous flow path between the introducer 14, the fluid passage 56 and the infusion component (such as the fluid line 12) to which the adaptor portion 46 is connected. The open aperture 80 fluidly communicates with the reservoir via the slots 92 extending between the leaf portions 88 of the radial leaf spring 84. As such, a medicament dispensed from the introducer 14 flows through the open aperture 80, and into the fluid passage 56 and reservoir 100.

Col. 9, lines 38-45. Mayer also states, "[i]n addition to flowing into the reservoir, such fluid flows directly into the fluid passage" (col. 4, lines 33-34). Thus, while fluid may flow continuously through a portion of the inner conduit that is in the direct flow path of the fluid passage 56, it does not appear that fluid flows continuously through the reservoir 100 in the Mayer device. When the reseal member is returned to its first position, Mayer explains that the fluid reservoir collapses and that "this collapse of the reservoir 100 causes the fluid previously introduced thereinto to be expelled from therewithin and into the fluid passage 56 via the slots 92 extending between the leaf portions 88 of the radial leaf spring 84" (col. 10, lines 5-9). Therefore, Mayer does not disclose or suggest that fluid may continuously flow through the entire inner conduit when the movable element is in the second position, as is recited in claims 4, 18 and 45. Accordingly, applicants respectfully submit that claims 4, 18 and 45, and their dependent claims 19-21, 28-30 and 46-49 are patentable over Mayer.

For the foregoing reasons, applicants respectfully submit that all pending claims are allowable over Mayer and request that the § 102(b) rejections be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 15-17 and 31-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mayer in view of Doyle (U.S. Patent No. 6,029,946). As discussed previously, Mayer fails to disclose or suggest, among other things, a movable element comprising a head defining a bore forming a part of the fluid passageway through the connector, the head being configured such that when the movable element is in the second position, the bore self-opens to permit fluid flow, as is recited in claims 1 and 18. Doyle likewise fails to disclose or suggest these features. As shown in FIGS. 7 and 8 of Doyle, as the plug 10 of needleless valve 2 is compressed by a nozzle 90 to its second or open position, a slit 22 in the plug 10 contacts the tip 64 of rod 14 and is "forced open as it passes over and around the tip 14" (col. 9, lines 54-58). As discussed in the specification at page 4, lines 4-9, connectors with internal cannulas, such as in Doyle, generally have disadvantages such as a lower fluid-flow rate caused by the small lumen

in the cannula and the risk that the pierced septum may be damaged with multiple uses, causing a leaking connector. There is no disclosure or suggestion in Doyle of a slit or bore that is self-opening, as in the claimed invention. Applicants believe that Mayer and Doyle, either alone or in combination, fail to disclose or suggest a bore that is self-opening to permit fluid flow as is recited in claims 1 and 18. Accordingly, applicants respectfully submit that claims 15-17 and 31-33, which are dependent from claims 1 and 18, respectively, are patentable over the cited references and request that the § 103(a) rejection be withdrawn.

CONCLUSION

Applicants have attempted to respond to each and every ground of objection and rejection set forth in the Office Action of September 23, 2003. In view of the foregoing remarks, it is respectfully submitted that all pending claims are allowable, and allowance is respectfully requested. Applicant requests reconsideration of the application.

Respectfully submitted,

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